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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

AGRAWAL, RITESH

ART UNIT	PAPER NUMBER
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1631

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/728,327	Applicant(s) JORGENSEN ET AL.	
	Examiner Ritesh Agrawal	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 March 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 37-55 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 37-55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicants' amendment and request for reconsideration in the communication filed on 3/5/07 are acknowledged and the amendments entered.

Claims 37-55 are currently pending and under consideration.

Withdrawn Rejections

2. The prior rejection of claims 37-55 under 35 U.S.C. 112, 1st paragraph is withdrawn in light of applicants' amendments filed 3/5/07.

The prior rejection of claims 37-55 under 35 U.S.C. 112, 2nd paragraph is withdrawn in light of applicants' amendments filed 3/5/07.

Claim Rejections-35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 37-41, 44-49, and 51-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hei, US 6,544,727, in view of Kobashi (U.S. Patent # 5,428,993 published July 4th, 1995). This rejection is modified from the previous rejection, but necessitated by amendment.

Hei discloses a system for the decontamination biological fluids (e.g., blood) (abstract and col. 66-68). Hei discloses a supply module (fig. 51, elements 508, 539, and 560). Hei discloses a cell module (fig. 51, elements 500, 528, and 538). Hei discloses a processing module (e.g., element 538 of fig. 51; a block disclosed on fig. 1

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and 3; an element where blood and a chemical is mixed on fig. 20B-C). Hei discloses a control module (fig. 5 1, element 550). Hei discloses a plurality of conduits connecting the supply module to the processing module, and the cell module to the processing module (fig. 49-5 1 and 20A-C). Hei discloses a plurality of valves adapted to the control module and other modules (ports, see fig. 49-51, 20A-C, and 37). Hei discloses a plurality of sensors, and specifically a sensor calculating the volume and weight of fluids (col. 65, line 30-47). Hei disclose controlling temperature (col. 71, line 63-65; col. 72, line 55-64), flow (col. 66, line 40-65) and volume (col. 68, line 14-40) and an optical device (col. 100, line 28-38). Hei discloses supply containers containing process chemicals (fig. 20,37, and 49-51; col. 68, line 14-67). Hei discloses phosphate salts, HEPES, citrates, physiological buffers, and anticoagulants (col. 69-70, col. 66, line 40-44). Hei discloses sterile docking, sterile filters, resin (chemical), sterile bags, sterile tubes, sterile tubing, and housing (col. 97, line 29-38 and claim 28). Hei discloses an in-line filter (claims 1 and 21). Hei discloses a centrifuge system (fig. 49-51, element 520). Hei discloses a heat transfer system (col. 72, line 53-67). Hei discloses processing chamber (element 538, fig. 51 and fig. 1). Hei discloses variable volume processing chamber (fig. 20 and 37; col. 97, line 40-65). Hei discloses an expression system (col. 97, line 40-67). Hei discloses an air module (col. 73, line 1-3). Hei discloses a waste module (a mesh pouch) (col. 121, line 45-61). Hei discloses pumps (elements 516, 506, 536, 526, and 556 of fig. 51). Hei discloses the blood cells as being erythrocytes (col. 12, line 18).

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Although Hei discloses sensors for calculating weight and volume of reinfused fluids and defining quantity of blood cells (col. 68, line 14-24; col. col. 65, line 30-47), Hei does not specifically disclose a weight sensor or confirming the correct delivery of a chemical by measuring a change in weight.

Kobashi discloses a weight sensor for chemical reagents to be used in automatic analyzers that confirms correct delivery of a chemical by measuring change in weight (for example, column 2, lines 1-25).

It would have been obvious, to one of ordinary skill in the art, at the time the invention was made, to modify the system of Hei to include the reagent weight sensor of Kobashi. One of ordinary skill in the art would have been motivated to do this because, as suggested by Kobashi, because it can prevent the wasting of reagents (for example, see abstract).

4. Claims 42-43 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hei, US 6,544,727, in view of Kobashi (U.S. Patent # 5,428,993 published July 4th, 1995), as applied to claims 37-41,44-49, and 51-54 above, and further in view of Matkovich, US 5,126,054.

Hei and Inoue make obvious the system of claims 37-41,44-49, and 51-54, as set forth above. Hei discloses a filter (claims 1 and 21), but Hei and Inoue do not disclose a filter having a median pore diameter of about 0.2 microns and a leukocyte depletion filter.

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Matkovich discloses the filtration of blood components into a receiving bag (col. 1, line 13-17 and claim 1). Matkovich further discloses removing leukocytes by filtration from blood (leukocyte depletion) (col. 1, line 13- 17; col. 5-6, bridging paragraph). Matkovich discloses a filter having 0.2 micron pores (claims 5 and 10).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to modify the system of Hei and Inoue to use a filter to deplete leukocytes, such as taught by Matkovich, where the motivation would have been to remove harmful components, as taught by Matkovich, col. 6, line 5-9.

5. Claim 55 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hei, US 6,544,727, in view of Kobashi (U.S. Patent # 5,428,993 published July 4th, 1995), as applied to claims 37-41, 44-49, and 51-54 above, and further in view of Hudak, US 5,641,637.

Hei and Inoue make obvious the system of claims 37-41, 44-49, and 51-54, as set forth above.

Hei and Inoue do not disclose the blood cell genotypes A, B, or AB.

Hudak discloses a method for preparing cells. Specifically, Hudak discloses rare genotype cells (e.g., AB genotype) (col. 2, line 45-52).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to modify the system of Hei and Inoue to use AB cells, such as taught by Hudak, where the motivation would have been to provide hospitals with rare cell genotype blood, as taught by Hudak, col. 2, line 45-52.

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6. Applicants' arguments have been fully considered, but they are not found persuasive.

For all of the above rejections, Applicants reiterate the argument that the combined references cannot teach of limitations of the any of the claimed inventions because the combined references do not provide for a weight sensor for providing the weight of process chemicals to a control module and using the weight to confirm whether a correct amount of process chemicals have been transferred (see remarks, page 7, 6th paragraph; page 9, 2nd paragraph; and page 9, 5th paragraph).

As argued above, Kobashi discloses a system for providing a weight sensor for providing the weight of chemical reagents (wherein the reagents, in the case of Hei, represent the process chemicals) and measuring changes in the weight of the process chemicals to confirm the transfer of the correct amount of reagent.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ritesh Agrawal whose telephone number is (571) 272-2906. The examiner can normally be reached on 8:30 AM - 5:00 PM M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ritesh Agrawal *RA*

John S. Brusca 31 May 2007
JOHN S. BRUSCA, PH.D
PRIMARY EXAMINER